

12 January 2010

REF: SHA/15406

APPEAL AGAINST NORTH LANCASHIRE PCT DECISION TO REFUSE AN APPLICATION BY ASSURA PHARMACY LTD FOR PRELIMINARY CONSENT PRIOR TO INCLUSION IN THE PHARMACEUTICAL LIST IN THE IMMEDIATE VICINITY OF OVER WYRE MEDICAL CENTRE, WILKINSON WAY, PREESALL, FY6 0EX

REF: SHA/15484

APPEAL AGAINST NORTH LANCASHIRE PCT DECISION TO REFUSE AN APPLICATION BY MERITUS LTD FOR PRELIMINARY CONSENT PRIOR TO INCLUSION IN THE PHARMACEUTICAL LIST AT OVER WYRE MEDICAL CENTRE, WILKINSON WAY, PREESALL, POULTON-LE-FYLDE, FY6 0FA

REF: SHA/15485

APPEAL AGAINST NORTH LANCASHIRE PCT DECISION TO REFUSE AN APPLICATION BY MERITUS LTD FOR PRELIMINARY CONSENT PRIOR TO INCLUSION IN THE PHARMACEUTICAL LIST WITHIN THE RETAIL AREA OF SANDY LANE, PREESALL, POULTON-LE-FYLDE, LANCASHIRE, FY6

1 The Application

By application dated 4 June 2009, Assura Pharmacy Ltd applied to North Lancashire Primary Care Trust ("the PCT") for preliminary consent prior to inclusion in the pharmaceutical list in the immediate vicinity of Over Wyre Medical Centre, Wilkinson Way, Preesall, FY6 0EX. In support of the application it was stated:

- 1.1 This application is both necessary and desirable in order to secure within the neighbourhood from which we intend to provide the services, adequate provision of pharmaceutical services.
- 1.2 The proposed neighbourhood is Knott End and Preesall, the boundaries of which are the open land to the east and south, with Morecambe Bay to the North and West. A map is included indicating the approximate neighbourhood boundaries. This neighbourhood definition has previously been accepted.
- 1.3 The neighbourhood currently contains one pharmacy and one medical centre. The existing pharmacy is located in Knott End in the west of the neighbourhood approximately 1.2km away from the medical centre. For residents in the Preesall area of the neighbourhood the distance is considerably further creating access difficulties. The application site is centrally located in the neighbourhood, resulting in improved access and will provide a choice of pharmacy services for the residents of the neighbourhood. With the next nearest pharmacy approximately 7km away by road there is no reasonable choice of pharmacy services or provider in the neighbourhood.
- 1.4 The proposed neighbourhood falls entirely within Preesall Ward. This ward has significantly higher percentages of residents reporting their health as not good (14.1%) or suffering from a limiting long-term illness (27.6%) than the national averages (9.0% and 17.9% respectively). In addition the ward has almost double the national average of residents aged 65 years or older with 29.6% compared to 15.9% for England. These statistics strongly suggest that the residents will have an above average demand for medical and pharmacy services.

- 1.5 Given the higher than average elderly population and the location of the neighbourhood's sole pharmacy access for many of the residents will be difficult.
- 1.6 The granting of this application will secure adequate pharmaceutical services in the neighbourhood.

By application dated 11 June 2009, Meritus Ltd applied to North Lancashire Primary Care Trust ("the PCT") for preliminary consent prior to inclusion in the pharmaceutical list at Over Wyre Medical Centre, Wilkinson Way, Preesall, Poulton-le-Fylde. In support of the application it was stated:

- 1.7 Meritus Limited propose to build a new purpose built pharmacy at the Over Wyre Medical Centre site which is in the neighbourhood of Preesall and Knott End on Sea. The population of Preesall and Knott End neighbourhood is in the region of 5730. The Over Wyre Medical Centre and Hambleton Branch Surgery provide general medical services to approximately 11,000 patients Over Wyre comprising Knott End, Preesall, Stalmine with Staynall, Hambleton, Pilling and Out Rawcliffe. The demographics of the local population show an above national average percentage of retired pensionable age groups. National projections show that this group will increase considerably in size from 16% in 2006 to 22% in 2031. Locally we would expect this percentage to be considerably higher and further increase demand on medical pharmaceutical and social services Over Wyre.
- 1.8 There have been small pockets of housing development in Knott End and Preesall over the last five years since Meritus last applied for a pharmacy contract at Over Wyre Medical Centre. However, we believe that future developments will be in the environs of the surrounding villages of Pilling and Hambleton which have been identified by Wyre Borough Council as having a housing deficit.
- 1.9 Meritus' previous application for a pharmacy at the Over Wyre Medical Centre in 2004 was granted by the Primary Care Trust on the grounds of being desirable, though not necessary. This decision was overturned on appeal. We now feel that following publication of the Government's White Paper "Pharmacy in England — Building on Strengths, Delivering the Future" and Anne Galbraith's "Review of NHS Pharmaceutical Contractual Arrangements", a new application is both desirable and necessary.
- 1.10 Meritus' previous application envisaged an in-house facility, however, we now feel that an on-site facility would be more appropriate. The Over Wyre Medical Centre site is approximately 1½ acres in size and comprises the Over Wyre Medical Centre and its associated car parking facility. There is a considerable amount of land surrounding the Medical Centre building which lends itself to development.
- 1.11 We feel a bespoke, purpose built, free standing, Pharmacy unit, situated near to the current Medical Centre facility would give maximum flexibility to further enhanced services at the Over Wyre Medical Centre site. We feel it would be possible to build a unit which could be future proofed to enable, for example, a further development which may attract dentistry provision on site and perhaps provide a base for a dedicated Over Wyre Social Services team in future.
- 1.12 The stand alone pharmacy building would also provide independently accessed office accommodation for use by community groups (e.g. Age Concern, Alzheimer's Society etc.) on an agreed sessional basis This facility is frequently requested from the Over Wyre Medical Centre but has been declined in recent years due to lack of consulting room availability.

By application dated 11 June 2009, Meritus Ltd applied to North Lancashire Primary Care Trust ("the PCT") for preliminary consent prior to inclusion in the pharmaceutical list within the retail area of Sandy Lane, Preesall, Poulton-le-Fylde, Lancashire, FY6. In support of the application it was stated:

- 1.13 Preesall forms the larger part of the Knott End and Preesall neighbourhood, both in area and population. The Wyre Borough Council census figures 2001 showed a total population of 5314. The population figures for patient numbers registered with Preesall Medical Centre show an increase in population to 5730 (May 2009 Appendix A). The demographics of the population show an above average percentage of retired pensionable age groups. National projection shows that this group will increase considerably in size from 16% in 2006 to 22% in 2031 (Appendix B). Locally we would expect this percentage to be considerably higher and further increase demand on medical, pharmaceutical and social services Over Wyre. Further housing developments in the area are, for geographical reasons, likely to be based in Preesall rather than Knott End. New commercial development is already gradually expanding in the Sandy Lane area of Preesall and the neighbourhood is increasingly assuming it's own identity.
- 1.14 Currently Preesall residents have to travel considerable distances for pharmaceutical services at Knott End pharmacy or even further to the nearest alternative provision at Hambleton. Bus services are infrequent and do not serve the populations of Pilling Lane at all. Traffic congestion and parking difficulties are already apparent at Knott End. At Preesall there is a large car park available at one end of Sandy Lane which is largely unused during business hours.
- 1.15 The Pharmacy will have a dedicated private consultation area allowing medicine usage reviews to be undertaken. We will recruit high quality staff including dispensing technicians and checkers, and work to develop the concept of the pharmacy as a "Centre for Healthy Living" by, for example, working with the Primary Care Trust to develop and engage in healthy initiatives such as smoking cessation, weight management, diabetes testing, NHS midlife checks and emergency contraception. The Pharmacy would be keen to work with the PCT to develop local pharmaceutical services identified as appropriate for the Over Wyre population. The Pharmacy would encourage patient/pharmacist communications through email and would embrace any new technological advances such as EPS etc.
- 1.16 A dedicated delivery vehicle will be adapted to enable the transportation of wheelchair patients to and from the Pharmacy, Preesall Medical Centre or Hambleton Health Centre as required, with the driver appropriately trained. The same vehicle would, of course, provide a high quality mobile delivery service on the lines of that already operated by the Hambleton Pharmacy, ensuring efficient deliveries to the housebound.
- 1.17 We believe this Meritus Ltd application for a new pharmacy contract in Preesall neighbourhood will provide the best opportunity for increased pharmaceutical services and diversification and convenience for the Preesall residents, and also for the residents of Over Wyre living further afield.

2 The PCT Decision

The PCT considered and decided to refuse all of the applications. The decision was sent to the appellants in a letter dated 2 October 2009. In a subsequent letter to all of the interested parties dated 6 October 2009, the PCT gave a further right of appeal to the applicants. The Decision report included with the letters states:

Introduction & Background

- 2.1 The Pharmacy Control of Entry Committee on 23 September 2009 on behalf of NHS North Lancashire determined these applications.
- 2.2 Full details of the applicant's proposals had been notified to various parties in accordance with the regulations and in determining the application the Committee took into account written representations from the Local Pharmaceutical Committee, Local Medical Committee, Assura Pharmacy Ltd, Lloyds Pharmacy, Meritus Ltd, all of

which had been copied to the applicant and other parties prior to determination of the application.

- 2.3 Meritus Ltd had submitted an application for a new, purpose built, stand alone pharmacy at the present Over Wyre Medical Centre site.
- 2.4 Meritus Ltd had also submitted an application for a Pharmacy to be located at 16 Sandy Lane, Preesall.
- 2.5 Assura Pharmacy Limited had submitted an application for a Pharmacy in the immediate vicinity of the Over Wyre Medical Centre, Wilkinson Way.
- 2.6 An application was received on 26 November 2003 by Meritus Ltd for preliminary consent for inclusion onto the pharmaceutical list under Wyre PCT at Over Wyre Medical Centre, Preesall. Wyre PCT approved the application on the grounds of desirability however this decision was overturned at appeal by the Litigation Authority in June 2004. The Committee concurred with the appeal submitted by Lloyds Pharmacy in that an additional contract in this neighbourhood was not necessary in order to secure adequate provision.

Description of the area and definition of neighbourhood

- 2.7 A site visit was undertaken by Margaret Kerfoot (Pharmacy/Optical Officer) on the 27 August 2009.

Suggested Neighbourhood

- 2.8 The Appeal Authority determined that 'the neighbourhood should be defined as Knott End and Preesall without recourse to specific boundaries'. Therefore the neighbourhood is defined as 'Knott End and Preesall'.
- 2.9 Knott End is defined as rural in character and therefore 'controlled'.

Current pharmacy provision

- 2.10 Lloyds Pharmacy 7 Wyre View Knott End FY6 0AE
- Distance from proposed pharmacy is 0.6 miles
 - Contracted opening times: 08:30am — 18:30pm M — F 09:00am – 17:00pm Saturday.

Doctors surgeries

- 2.11 Over Wyre Medical Centre – Wilkinson Way Off Pilling Lane Preesall FY6 0FA
- Open: Monday and Wednesday 07:15am – 20:00pm; Tuesday, Thursday and Friday 07:15am – 20:00pm
 - Distance from proposed Pharmacy – On Site.
- 2.12 Hambleton Health Centre — Kiln Lane Hambleton FY6 9AH
- Branch of Over Wyre Medical Centre – Open: 09:00 am— 10:00am Monday to Friday
 - Distance from Proposed Pharmacy – 7 km

Consideration by the Committee

- 2.13 Under regulation 24(7) the PCT has discretion to consider together two or more applications.
- 2.14 The Committee noted that these were multiple applications and the determination should be based on a consideration of all the evidence provided to the PCT about the competing claims of the applicants. It was agreed that in such cases a favourable determination should not be made simply on the grounds that one particular

application was received before another. It should be made on the basis that the range and quality of services specified in the application in question is to be preferred.

- 2.15 The committee considered the following points:
- 2.15.1 The range and availability of services to be provided
 - 2.15.2 The times at which such services are to be available
 - 2.15.3 There is a realistic prospect that services will be provided (for example the applicant has secured or will secure the relevant premises)
 - 2.15.4 Access for the disabled or [sic]
 - 2.15.5 The provision of staff with specialist language or interpreter skills
- 2.16 The Committee also considered the prejudice test and the necessary desirable test.
- 2.17 The committee discussed whether there had been any significant changes in the neighbourhood since the previous application and noted that there had been no further housing developments and the population figures obtained from the Census Area Statistics show little increase in recent years.

Decision

- 2.18 The conclusions of the discussions were that there had been insufficient changes in the environment from the previous applications five years ago to make an alternative decision to that of the Litigation Authority. The committee all agreed that all three applications should be refused on the grounds that they were neither necessary nor desirable.
- 2.19 **AGREED:** All three applications be refused.

3 The Appeals

In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority ("the Appeal Unit"), dated 8 October 2009, Assura Pharmacy Limited appealed against the PCT's decision. The grounds of appeal are:

- 3.1 It is submitted that the PCT has placed too much weight on the previous decision, arrived at over 5 years ago, instead of considering the application afresh.
- 3.2 The PCT state that there have been insufficient changes since the previous decision to make an alternative decision. A highly significant change since this previous decision is the introduction of the NHS (Pharmaceutical Services) Regulations 2005 and in particular the criteria of 'choice'.
- 3.3 The PCT give no indication that they considered whether there was a reasonable choice of service providers in the neighbourhood. As there is only one pharmacy in the defined neighbourhood it is submitted that had the PCT considered this they would have found that there was in fact no choice. Given the distance to the next nearest pharmacy it is submitted that this should have been a key consideration for the PCT.
- 3.4 The PCT state that there had been no housing developments and the population figures had shown little increase in recent years. It is submitted that there has been residential developments since this time and in particular near to the application site. National Statistics states that the population of Preesall Ward has grown by nearly 10% between 2001 and 2008.

- 3.5 The introduction of the new pharmacy contract in 2005 has also greatly changed the way in which pharmacy services are delivered, with a greater emphasis on advanced and enhanced services. It is submitted that what was considered adequate in 2004 is not necessarily adequate today.

In a letter to the Family Health Services Appeal Unit of the NHS Litigation Authority ("the Appeal Unit"), dated 2 November 2009, Meritus Ltd appealed against the PCT's decision. The grounds of appeal are:

- 3.6 I wish to appeal against the PCT's decision to refuse the above applications. I wish this letter of appeal to apply to both applications and request that they both be reconsidered. I would like to thank the PCT for their diligence, and whilst respecting their decision to reject these applications, I would respectfully suggest that not enough weight might have been placed on the following arguments.

3.6.1 There has been an increase in population numbers, the vast majority of which reside to the east of the Over Wyre Medical Centre ie further away from the present Lloyds Pharmacy. The retail provision in the village of Preesall (just within the one mile limit from Lloyds Pharmacy) is increasing and is a centre for day to day living for increasing numbers of people in the immediate locality and around. There is no question that at the Over Wyre Medical Centre it is a very frequent request that medications be dispensed at the Dispensary by non-dispensing patients who live to the east of the Medical Centre and do find that the distance entailed on foot, particularly if elderly and infirm, or young with prams etc, can be excessive. When these requests are inevitably refused the patients voice their frustrations and frequently their anger. At the time of the last application in 2004 the local Preesall Parish Council was in support of the previous application to site a new pharmacy at the Over Wyre Medical Centre citing patient convenience.

3.6.2 The patients of this area of Preesall have an increasing choice when it comes to their retail purchases and services provisions locally in the Preesall area, and we believe that many of them would love to have the choice of provider of their pharmaceutical needs.

- 3.7 I would respectfully request that the decisions to refuse the above applications be reconsidered on the grounds of their desirability and provision of patient choice.

4 **Summary of Representations**

This is a summary of representations received on the appeals. A summary of those representations made to the PCT are only included in so far as they are relevant and add to those received on the appeal.

4.1 NORTH LANCASHIRE PCT

4.1.1 In this response we have referred to Assura Limited as the "First Appellant" and Meritus Limited as the "Second Appellant". The National Health Service (Pharmaceutical Services) Regulations 2005 and individual provisions thereof are referred to as "the Regulations" and "Regulation xx" respectively.

4.1.2 The PCT further relies upon the contents of its Decision Report dated 2 October 2009 and its Draft Pharmaceutical Needs Assessment dated January 2009 (both enclosed). While not as yet approved by the PCT's Board, the substantive contents of the Pharmaceutical Needs Assessment are thought unlikely to change and give a useful overview of the provision of, and assessed need for, pharmaceutical services within the PCT's area.

4.1.3 We would respond to the grounds of appeal submitted by the appellants as follows:

- 4.1.4 The First Appellant seeks to identify a gap in the PCT's reasoning by citing the phrase in its Decision Report of 2 October 2009 that there had been no "significant changes" since the time of the previous application. In the PCT's submission this misrepresents the PCT's stance which was that there had been "no significant changes in the neighbourhood (emphasis added) since the time of the last application.
- 4.1.5 The PCT had regard to the demographic changes and pattern of development in the neighbourhood since the time of the previous application and noted that, while certain changes had occurred, these were not significant. The First Appellant cites a 10% increase in the population of Preesall Ward between 2001 and 2008. While this is a large relative increase, in absolute terms this translates to a population increase of only 513 people. The PCT took the view that this increase was not significant and therefore insufficient to make it necessary or desirable for there to be an additional pharmacy in the neighbourhood.
- 4.1.6 The First Appellant asserts that the PCT has placed too much weight on the previous decision of the Appeal Unit dated 11 June 2004. The PCT would reply that it gave due regard to the changes in the neighbourhood since the time of the previous application and did not simply defer to the decision of the Appeal Unit. It also gave careful consideration to the applications made by both the Appellants as evidenced by the five bullet points set out at Paragraph 5 of the Decision Report. However, it found these changes to be of insufficient degree to warrant granting the application in accordance with the 'necessary or desirable' criteria. In the PCT's submission the mere fact that it reached a decision which concurred with that reached by the Appeal Unit in 2004 is not sufficient to prove that that decision represents a failure by the PCT to exercise its discretion because of undue deference to the Appeal Unit's previous decision.
- 4.1.7 The PCT is of course aware of the introduction of the requirement to have regard to issues of "reasonable choice" under Regulation 12(2)(b). The PCT considered "the range and availability of services to be provided" which entailed an evaluation of the applications made by both the First and Second Appellants relative to current provision in the area.
- 4.1.8 While ensuring reasonable choice forms a subsidiary test under Regulation 12 to which the PCT has given due regard, the primary test is that of adequacy. The PCT has not identified any inadequacy in the current provision of community pharmacy services in the neighbourhood. This is supported by the lack of any such reference in the Draft PNA.
- 4.1.9 The PCT is further required to have regard to "any other information available to the Primary Care Trust which, in its opinion, is relevant to the consideration of the application" (Regulation 12(2)(c)). The PCT is mindful in this regard of the costs associated with the commencement and ongoing costs of new community pharmacy contracts. The Appeal Unit is asked to have regard to the passage headed "The financial impact of pharmacy commissioning" at Page 44 of the Draft PNA. It is estimated that each additional pharmacy contract costs the PCT £60,000 per year. The PCT submits that it is reasonable for it, in accordance with Regulation 12(2)(c), to have regard to the limited resources available to the health service now and in the foreseeable future when determining whether to commission one or more pharmacy contracts for which there is no identified need.
- 4.1.10 The PCT acknowledges that there are arguments in favour of the co-location of community pharmacy and primary medical services as would be entailed to a greater or less extent in the applications made by both Appellants given the proximity of the planned sites to the Over Wyre Medical Centre. However, in the PCT's submission there are also countervailing arguments in favour of

ensuring an appropriate spread of accessible health services across a neighbourhood. This is particularly relevant in the case of the current applications as the current pharmacy is located within Knott End which is the main commercial and services centre in the Over Wyre locality while the applicant's sites are located in Preesall. As outlined at paragraph 2 above the recent and projected population increase for the neighbourhood are not, in the PCT's submission, sufficient to sustain two pharmacies. It is therefore foreseeable that, by granting any of the current applications, this may have a significant impact on the viability of the existing community pharmacy in Knott End, thereby adversely affecting the distribution of accessible health services within the neighbourhood.

- 4.1.11 The PCT has considered such issues within its Draft PNA at Page 43 which, while specifically addressing the issue of new-build primary care centres are, in the PCT's submission, relevant considerations in respect of the current applications. The PCT relies in particular upon the following extracts:

There may be a requirement for the relocation of pharmacy services to continue to meet the needs of our population where there are new primary care developments planned. These developments do not create additional demand for pharmaceutical services but will reshape the pattern of demand in response to changes in the way in which patients access services. The pharmacy element of these developments will need to be carefully planned to ensure that there remains good access to pharmacy services for patients in the wider network.

Where these developments take place the PCT will endeavour to achieve a planned transition for pharmacy services such that changes do not adversely impact the remaining pharmacy network to the detriment of patients. The PCT will pay particular attention to where movement of GP services is also likely to result in the movement of pharmacy services out of a community. Specifically the PCT will seek to mitigate the compound effect of relocation of GP and pharmacy services from neighbourhoods and communities. This may be achieved by commissioning pharmacies in these areas to provide a wider range of services to support the patient population. (emphasis added)

- 4.1.12 The First Appellant further relies upon "a greater emphasis on advanced and enhanced services" since the introduction of the Regulations as a basis upon which its application should be granted. It is noted that both Appellants have indicated a willingness to provide Local Enhanced Services from their proposed premises as required. However, it is acknowledged by both Appellants that there may currently be no identified need for these services in the neighbourhood. The PCT would also confirm that, in so far as it is aware, this is indeed the case in that there have been no requests from those within the neighbourhood for such services. Similarly, the PCT has not identified a particular unmet need in respect of enhanced services in the neighbourhood (or indeed the wider Wyre locality) which these applications might serve to meet. The PCT would further advise that it has not sought to commission any enhanced services from the pharmacy presently operating in the neighbourhood which it has subsequently declined to provide.
- 4.1.13 It is acknowledged that there are certain enhanced services which the PCT would prefer to make available across the entirety of its area such as Emergency Hormonal Contraception as evidenced at page 78 of the Draft PNA. However, in view of the constraints on the PCT's resources referenced above, these being both current and predicted for the foreseeable future, the PCT considers it unlikely that it would be able to avail of the willingness by these applicants to provide a range of enhanced services.
- 4.1.14 The PCT therefore reiterates the view set out in its Decision Report of 2 October 2009 that it is neither necessary nor desirable to grant any of the

three applications which form the subject matter of this appeal in order to secure the adequate provision of pharmaceutical services in the Preesall neighbourhood.

- 4.1.15 The PCT reserves the right to expand on these representations in the event that the Appeal Unit consider it necessary for this matter to proceed to an oral hearing.

4.2 ASSURA PHARMACY (comments on all three applications)

Neighbourhood

- 4.2.1 The neighbourhood has been agreed by all parties as the town of Knott End and Preesall. This is also the neighbourhood defined in a previous appeal held in 2004 RE: SHA/11806.
- 4.2.2 It is submitted that if specific neighbourhood boundaries are required then the ward boundaries for Preesall Ward form appropriate boundaries.
- 4.2.3 Although there has been residential and commercial developments since the previous appeal it is submitted that this neighbourhood definition is still appropriate.

Neighbourhood Demographics

- 4.2.4 Based on the 2001 census Preesall Ward had a resident population of 5,314. The Office of National Statistics estimates that the population had grown to 5,827 by June 2008. It is submitted that the resident population of the neighbourhood is circa 6,000 today.
- 4.2.5 This population figure does not account for the temporary residents and visitors that will utilise the neighbourhood's caravan parks, especially in the summer period. During the summer periods the population of the neighbourhood will increase significantly due to the increase in holiday makers and workforce during this period. The reliant population can therefore be significantly in excess of 6,000.
- 4.2.6 The ward contains an unusually high number of elderly residents with 36.6% aged 60 or over, compared to 20.8% nationally. This is reflected in the high mean age of the ward of 47.0 years compared to a national average of 38.6 years.
- 4.2.7 The percentage of retired residents is almost double the national average at 25.9% compared to 13.5% nationally.
- 4.2.8 This high elderly population inevitably has an impact on the general health of the neighbourhood with 14.1% reporting their health as 'not good' and 27.6% suffering a limiting long-term illness (compared to 9.0% and 17.9% respectively nationally).
- 4.2.9 The high elderly population ensures there is an unusually high demand for medical and pharmaceutical services in the neighbourhood. This is clearly demonstrated by the Over Wyre Medical Centre issuing approximately double the number of prescriptions per head of population as the national average.
- 4.2.10 The gradual increase in the neighbourhood population demonstrates the steady but significant residential developments that have occurred over recent years. The vast majority of the population growth has occurred around or to the east of the application site.

Access to Pharmacies

- 4.2.11 The neighbourhood contains one pharmacy, Lloyds Pharmacy - 7 Wyre View, which is approximately 0.8 miles from the medical centre and application site. The next nearest pharmacy is the Hambleton Pharmacy located over 4 miles away.
- 4.2.12 For the considerable population living to the east of the medical centre the distance that they must travel to access the neighbourhood's sole pharmacy will be considerably more than 0.8 miles.
- 4.2.13 Although Assura accepts that Knott End and Preesall are within the same neighbourhood they originated as separate villages and have slowly merged overtime. However they have retained much of their identity and facilities.
- 4.2.14 For the residents living to the east of the medical centre (in Preesall) there is little need for them to travel to Knott End as part of their daily routine. The typical neighbourhood shops on Sandy Lane provide for their daily needs and the neighbourhood's three schools are all located to the east of the medical centre.
- 4.2.15 The neighbourhood has fairly typical levels of car ownership, with one in five houses not having access to a vehicle, but relatively limited public transport facilities. This combined with the high elderly population ensures that movement around the neighbourhood is not particularly easy for many.
- 4.2.16 It is submitted that given the high elderly population a return journey of over 1.5 miles to access the nearest pharmacy is, at the very least, inconvenient and for many simply not a feasible journey.
- 4.2.17 The courts have made it perfectly clear that convenience is a ground to consider. Beldam LJ observed in *ex parte E. Moss Ltd*, Transcript p. 22, that convenience is not an irrelevant consideration", the relevant passage is quoted below;
- "To decide whether it is desirable to grant an application in order to secure adequate provision of services in a neighbourhood, the Authority has to compare the advantages with the disadvantages of doing so by using its judgment based on local knowledge and observation, present circumstances and future expectations. **Convenience is not an irrelevant consideration.**"* (emphasis added).
- 4.2.18 The Over Wyre Medical Centre is open until 6.30pm on weekdays, with extended opening until 8pm on Mondays and Wednesdays. The Lloyds Pharmacy closes at 6pm on weekdays, clearly leaving a significant period every evening when the surgery is open, but the nearest pharmacy is closed.
- 4.2.19 Even for patients with access to private transport they would need to leave the surgery by about 5.30pm in order to travel to Lloyds Pharmacy and get a prescription dispensed before the pharmacy closes at 6pm.
- 4.2.20 Assura Pharmacy is proposing to open for an additional hour every weekday compared to Lloyds and will happily extend the opening hours on Mondays and Wednesdays to match those of the surgery if required.

Choice in the Neighbourhood

- 4.2.21 The previous application was considered under the 1992 Regulations.

- 4.2.22 Under the NHS (Pharmaceutical Services) Regulations 2005, reasonable choice of both contractor and services has been included as a matter which the PCT and Appeal Unit are obliged to have 'particular regard' to.
- 4.2.23 In the recent review of the Control of Entry Regulations, the government specifically set out the reasons for the explicit inclusion of choice in the 2005 Regulations. The reasons included
- 4.2.23.1 Promote consumer choice and harness the benefits of increased competition.
- 4.2.23.2 Improve further the accessibility and convenience of pharmaceutical services.
- 4.2.24 Choice is part of the overall test of adequacy, but nevertheless must be considered in each application for inclusion in the Pharmaceutical List.
- 4.2.25 There is no choice of pharmacy services in the proposed neighbourhood.
- 4.2.26 It is important to note that there is no requirement for an Applicant to 'prove' that there is a demand for choice in the neighbourhood. The Regulations state that the PCT and Appeal Unit shall have regard in particular to whether or not reasonable choice exists.
- 4.2.27 The amount of weight to be given to the issue of choice is for the Appeal Unit to decide. It must however be noted that the amount of weight must be decided upon after consideration of the particular neighbourhood and the demand for services (or a choice of services). In particular it must be noted that the amount of weight given to this issue must be based on sensible and defensible criteria.
- 4.2.28 It is submitted that with a significant distance to the nearest pharmacy, an elderly resident population of approximately 6,000 and a long distance to the next nearest pharmacy, the issue of 'reasonable choice' should be an important consideration for the appeal unit.
- 4.2.29 Given that the previous application was considered approximately 5 years ago under the previous Regulations, it is submitted that it is appropriate for the issue of adequacy in the neighbourhood to be reassessed. This is especially true given that both Assura and the local GPs have submitted applications that state existing services are not adequate.

Competing Applications

- 4.2.30 Two other applications have been submitted by Meritus Ltd for the same neighbourhood, one for Sandy Lane and another also for the Over Wyre Medical Centre.
- 4.2.31 Assura Pharmacy agrees with Meritus that a second pharmacy in the neighbourhood is both necessary and desirable, or at the very least, desirable. It is submitted that a pharmacy at the medical centre is preferable to Sandy Lane as this is the centre of highest demand for pharmacy services.
- 4.2.32 The two applications from Meritus Ltd have both stipulated over 40 contracted hours per week and as such neither can be granted, as the introduction of the NHS (Pharmaceutical Services) (Amendment) Regulations SI 2006/3373 stipulates that core contracted hours must be 40.
- 4.2.33 The fact that an applicant must stipulate 40 contracted core hours is stated on the PSNC website which states "There was some uncertainty about

whether a pharmacy could declare more than 40 core contractual hours — but this was finally clarified in January 2007, when the Regulations were amended to state that a pharmacy core contractual hours must be 40 (or 100 for the exemption)” and also the recently updated Information for PCTs states “The requirements for core contractual hours are 40 hours per week for pharmacies and 30 hours per week for appliance contractors - unless fewer or more hours are agreed with or directed by the Primary Care Trust or on appeal by the Appeal Unit (schedule 1, paragraph 22; schedule 3, paragraph 10). Primary Care Trusts should note that under SI 2006/3373, the previous wording of “not less than 40 hours” for pharmacy contractors changed and now only refers to “40 hours”.

- 4.2.34 A recent appeal decision REF: SHA/15212 found that where an applicant had incorrectly stated their core hours “The Committee accepted that this was an error on the applicant’s part however were of the view that a mandatory requirement had not been met and an application may not subsequently be amended”. It is acknowledged that this case was for a 100 hour contract, but it is submitted that the same principles apply in this case — a mandatory requirement (ie to stipulate 40 core hours) has not been met.
- 4.2.35 It is submitted that the application from Assura is the only valid application and therefore the only application that can be granted.

Service Provision

- 4.2.36 Since the previous application was heard the new pharmacy contract has been implemented specifically aimed at increasing the range of services available from pharmacies.
- 4.2.37 As indicated on the application form Assura Pharmacy will provide all the locally enhanced pharmacy services commissioned by the PCT. In addition to these services, where there is a need Assura Pharmacy provides the following services from their pharmacies:
- 4.2.37.1 Lipotrim Weight Management Programme
 - 4.2.37.2 Gastroview 3-in-1 Indigestion test
 - 4.2.37.3 Free Prescription Collection & Delivery Service
 - 4.2.37.4 Blood Pressure Monitoring
 - 4.2.37.5 Cholesterol Testing
 - 4.2.37.6 Diabetes Testing
 - 4.2.37.7 Pregnancy Testing
- 4.2.38 All pharmacists employed will be qualified to provide Medicine Use Reviews (MUR’s) and the premises fitted out in such a way to provide a private consultation room. Assura Pharmacy ensure they have more than adequate staffing and second pharmacist cover to enable the delivery of MUR in a professional manner from dedicated consulting rooms. The pharmacy will also be fitted with the relevant IT connectivity to enable electronic transmission of prescriptions.

Conclusion

4.2.39 This application is both necessary and desirable to secure adequate pharmaceutical services in the neighbourhood for the following reasons:

4.2.39.1 The neighbourhood has an unusually high elderly population which results in a very high demand for both medical and pharmacy services.

4.2.39.2 The nearest pharmacy is approximately 0.8 miles from the medical centre and application site. With the high percentage of elderly residents and limited public transport this is a considerable distance.

4.2.39.3 There is no choice of pharmacy services or provider in the neighbourhood, with the next nearest pharmacy over 4 miles away (one way).

4.2.39.4 This application will provide extended opening times during the week, at times when the medical centre is open, but the Lloyds Pharmacy is closed.

4.2.39.5 Since the previous application the population has continued to grow and age, which combined with the introduction of the new 2005 Regulations and the new pharmacy contract, ensures that this application is both necessary and desirable.

4.2.39.6 The application from Assura Pharmacy is the only valid application being considered.

4.2.40 The granting of this application will remedy all the above issues and secure adequate pharmaceutical services in the neighbourhood.

4.3 LLOYDS PHARMACY (comments on case ref: 15406)

4.3.1 North Lancashire PCT has provided a detailed decision regarding its consideration of the application and we submit they have arrived at the correct decision.

4.3.2 We stand by the comments made in our original submission that the population of Knott End and Preesall is not large. The Appeal Committee previously took into account any projected new housing and concluded that it was of a sufficiently small scale and unlikely to render the provision of pharmaceutical services to be inadequate.

4.3.3 The applicant/appellant has not provided any evidence of inadequacy and the PCT confirm that adequate pharmaceutical services are already provided to the neighbourhood population.

4.3.4 For the above reasons we respectfully ask the FI-IS Appeal Unit to uphold the decision of the PCT, dismiss the appeal and refuse the application as wholly adequate pharmaceutical services are already provided to patients, residents and visitors.

4.4 LLOYDS PHARMACY (comments on case ref: 15484)

4.4.1 North Lancashire PCT has provided a detailed decision regarding its consideration of the application and we submit they have arrived at the correct decision.

4.4.2 None of the evidence in the appeal suggests that there is currently any inadequacy in the current provision of pharmaceutical services. The only comment is regarding Meritus believing residents 'would love to have the

choice of provider of their pharmaceutical needs'. The regulations were not designed to place a pharmacy on every street corner or in every location.

4.4.3 We would stand by the comments we submitted to the PCT and we would also ask the Appeal Unit to note that a previous consideration determined that adequate pharmaceutical services were already provided in the neighbourhood. We have not seen any evidence from this appeal that this does not remain the case.

4.4.4 For the above reasons we respectfully ask the FHS Appeal Unit to uphold the decision of the PCT and refuse the application and dismiss the appeal as wholly adequate pharmaceutical services are already provided to patients, residents and visitors.

4.5 LLOYDS PHARMACY (comments on case ref: 15485)

4.5.1 North Lancashire PCT has provided a detailed decision regarding its consideration of the application and we submit they have arrived at the correct decision.

4.5.2 None of the evidence in the appeal suggests that there is currently any inadequacy in the current provision of pharmaceutical services. The only comment is regarding Meritus believing residents 'would love to have the choice of provider of their pharmaceutical needs'. The regulations were not designed to place a pharmacy on every street corner or in every location.

4.5.3 We stand by our comments submitted in our letter to the PCT. The Appeal Unit has also previously considered provision to be adequate and dismissed the Appeal.

4.5.4 We would stand by the comments we submitted to the PCT and we would also ask the Appeal Unit to note that a previous consideration determined that adequate pharmaceutical services were already provided in the neighbourhood. We have not seen any evidence from this appeal that this does not remain the case.

4.5.5 For the above reasons we respectfully ask the FHS Appeal Unit to uphold the decision of the PCT and refuse the application and dismiss the appeal as wholly adequate pharmaceutical services are already provided to patients residents and visitors.

4.6 CENTRAL LANCASHIRE LPC (comments on all cases)

In a letter to the PCT dated 20 July 2009, the LPC stated:

4.6.1 The committee discussed the definition of the neighbourhood and considered it to be that of Knott End & Preesall. Census statistics 2001 show a population of just over 5000 residents. Although there is evidence of some new housing, it is not great in number and therefore population numbers will not have risen greatly since 2001.

4.6.2 The committee noted a previous application for the same neighbourhood made in 2004. This application was approved by the then Wyre PCT but the decision was overturned on appeal (ref 11086), the conclusion being that an additional contract (to the already existing one) was not necessary in order to secure adequate provision.' It went on to say 'the committee is mindful of the advantages sought by the applicant e.g. to improve services, but were also mindful that in order for desirability to prevail then a gap in pharmaceutical services must be proven to the extent that adequacy is not presently served.'

- 4.6.3 It is the opinion of the LPC that current pharmaceutical provision remains adequate and the committee is not aware of any complaints regarding the current provision in the neighbourhood.

5 Unsolicited Comments

5.1 OVER WYRE MEDICAL CENTRE

- 5.1.1 This submission is in response to the Appeal responses references as above.
- 5.1.2 The practice has received no complaints regarding the adequacy or competency of the local pharmaceutical services provided by the chemist in Knott End and Preesall neighbourhood.
- 5.1.3 There has been some minimal population increase since 2004. No major population increases in the neighbourhood are planned.
- 5.1.4 The practice has increased the number of full time equivalent partners this year from five to five and three quarters reflecting advance planning for the impending complete retirement of two partners who are currently part time. This increase was not due to increased workload.
- 5.1.5 This is a dispensing practice providing full dispensing doctor dispensing services to approximately 3,500 patients in the outlying areas covering 80 square miles.
- 5.1.6 The Knott End Pharmacy provides free daily delivery services to patients in all areas of the Practice. The more distant Hambleton Pharmacy provides twice daily free delivery services, again to all area of the Practice. Both pharmacies enthusiastically and competitively deliver to the Knott End and Preesall neighbourhood. I must state that the Over Wyre Medial Centre has had no communications with Assura and as far as I am aware no suitable premises are available in the declared locality on their application, as it is purely residential.
- 5.1.7 We believe that the pharmaceutical services currently provided are adequate and do provide patient choice of provider particularly with at least three daily deliveries from two competing pharmacies available for any patient of the Practice five days a week.
- 5.1.8 Assura has adduced no evidence to show that pharmaceutical services are inadequate in the neighbourhood other than the choice of providers and therefore on the spectrum of adequacy and inadequacy their application falls far short of that required to prove on the balance of probabilities that the application is desirable/expedient and in no way can be considered to be necessary to secure the adequacy of pharmaceutical services in the neighbourhood.
- 5.1.9 The PCTs initial rejection of all three applications, we feel is the correct decision.

6 Observations on Representations

6.1 ASSURA PHARMACY LTD

- 6.1.1 Assura Pharmacy stand by their submission that pharmacy services in the neighbourhood are not adequate.

- 6.1.2 Meritus Ltd has always maintained that pharmacy services in the neighbourhood are not adequate and have stated this on many occasions in both the above applications and the previous application.
- 6.1.3 As Meritus Ltd give no reasons for their sudden change of opinion it is assumed that, after receiving copies of the appeals, they have realised that their applications are not valid (due to them stipulating greater than 40 core hours). It would appear that Meritus Ltd are now trying to prevent the only valid application (the one from Assura) being granted.
- 6.1.4 For the reasons above the letter from the Over Wyre Medical Centre dated 24 December 2009 should not be given any weight.

7 Consideration

- 7.1 The Pharmacy Appeal Committee appointed by the Family Health Services Appeal Unit of the NHS Litigation Authority, ("the Committee") had before it the documentation considered by the PCT, a map of the area showing the proposed premises in Preesall, the location and dispensing figures for pharmacies in the area, the surgeries in the area, together with the responses to the Authority's own consultations. On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 7.2 The Committee noted that Preesall is in a controlled locality, however the Committee had no reason to believe that Preesall is a reserved locality and noted that no appeal in respect of this determination had been received. The Committee concluded that Preesall is not a reserved locality and therefore the prejudice test would apply.
- 7.3 As such, the application which is made under provision of Regulation 5(1)(a) of the National Health Service (Pharmaceutical Services) Regulations 2005 (as amended) ("the Regulations") falls to be determined under the provisions of Regulations 18ZA and 12.
- 7.4 The Committee noted that the PCT had also considered the prejudice test and the necessary and desirable test. The Committee noted that no formal determination had been made by the PCT as to whether any of the applications considered would prejudice the proper provision of primary medical services or pharmaceutical services. The Committee noted that no appeals with regards to the "prejudice" test had been received.
- 7.5 The Committee noted that the PCT had determined that all of the applications should be refused as they were neither necessary nor desirable.
- 7.6 On the basis of the decision of the PCT, the Committee considered whether the proposed pharmacies were necessary or desirable to secure the adequate provision of pharmaceutical services in the neighbourhood. The Committee had regard to Regulation 12(1), the necessary or desirable test, and, in considering that test, had regard in particular to Regulation 12(2), (3) and (4) of the National Health Service (Pharmaceutical Services) Regulations 2005 (as amended) ("the Regulations").
- 7.7 The Committee dealt with the application by way of reconsideration of all the issues.
- 7.8 The Committee noted that the neighbourhood as defined previously by the PCT had not been disputed on appeal. The Committee accepted this neighbourhood without prejudice to any future applications.
- 7.9 The Committee noted that there was currently one pharmacy located to the west of the neighbourhood in Knott End on Sea, approximately 0.6 miles from the only medical services in the neighbourhood. In the Committee's view it is not axiomatic that a contract is needed within a neighbourhood presently containing one pharmacy

in order to secure adequacy. While there is no choice within the neighbourhood, the level of adequacy may be dependent on pharmaceutical services elsewhere. However in this instance, the Committee viewed the provision of pharmaceutical services from outside the neighbourhood to be marginal.

- 7.10 The Committee noted the comments with regard to the enhanced and advanced services and the comments from both applicants that they would be willing to provide all services commissioned by the PCT, the Committee noted that there is no suggestion that the existing pharmacy is not currently providing essential and directed services as commissioned by the PCT. The Committee also noted that no gaps had been identified by the PCT in the PNA. The Committee was of the view that the applicants had relied upon their offers of services rather than a gap, or potential gap in the current provision. The Committee had no reason to believe that the existing pharmacy would not offer enhanced or advanced services if commissioned by the PCT, if funding was available to the PCT.
- 7.11 Given the above, the Committee considered that the current provision of pharmaceutical services could not be said to be wholly inadequate and therefore an additional pharmacy contract in the neighbourhood was not necessary. The Committee went on to consider, on the spectrum of adequacy, whether an additional pharmacy contract was desirable, and if so which applicant was best placed to secure that adequacy.
- 7.12 The Committee noted that both of the appellants had stated that the population has increased since the previous application 5 years ago. The Committee noted the assertions that the main housing developments were to the east of the neighbourhood in Preesall rather than in Knott End on Sea where the current pharmacy is located. The Committee noted the distance to the nearest pharmacy, which is not significant or disputed by parties. The Committee is of the view however that distance of itself does not result in an inadequacy of pharmaceutical services. The Committee noted the information provided by one of the applicants to suggest that due to the large proportion of elderly within the neighbourhood access to pharmaceutical services, especially at such a distance, is not adequate. The Committee noted however that no information had been provided to suggest that those on foot who were willing and able to do so could not access existing pharmacies or that those who had the use of a car would not be able to access existing pharmaceutical provision either within the neighbourhood or in adjacent neighbourhoods.
- 7.13 The Committee noted that one of the applicants (Assura) seeks to offer extended opening times to match those of the surgery. However the Committee noted that these hours were supplementary hours, which could be altered with 90 days notice. The Committee was of the view that the difference in hours was marginal and that there was no evidence that there was a need at such additional times. The Committee concluded that if there was a shortfall for whatever reason, it could be remedied by the PCT using the power that it has under the Regulations to direct the existing pharmacy to open for additional hours where it considers there is a need to do so in order to meet the pharmaceutical needs of people in the neighbourhood.
- 7.14 The Committee noted the comments with regard to convenience, however the Committee was aware that convenience is not a factor to be considered alone unless the degree is sufficiently high on the scale to suggest it would contribute to a gap in provision.
- 7.15 The Committee accepts that regard must be had to the fact that any alternative providers, and thereby services, are outside of the neighbourhood and that this could be seen as a potential gap for the size and make up of the population. However, on balance, the Committee determined that neither of the applicants had demonstrated, the onus being on the applicants, that there is a gap on the spectrum of adequacy sufficient to conclude that the provision of pharmaceutical services is not currently secured to the standard of adequacy.

- 7.16 In the Committee's view, taking into account the circumstances considered pertaining to the neighbourhood in question, balancing the current provision within that neighbourhood together with any potential advantage that could be gained by granting a further contract, in particular by way of access and a reasonable choice of provider, given that a purpose of being in that neighbourhood may be to access primary medical services from which pharmaceutical services may be required by the reliant population, then the Committee determined that pharmaceutical services were currently secured to the extent that it was neither necessary nor expedient to grant the applications.

8 **Decision**

The Committee was of the view that an additional pharmacy was neither necessary nor expedient to secure the adequate provision of services in the neighbourhood. Accordingly the Committee dismisses the appeals.

Jill Jackson
Appeal Officer

A copy of this decision is being sent to:

Assura Pharmacy Ltd
Meritus Ltd
Lloyds Pharmacy
Over Wyre Medical Centre
Central Lancashire LPC
Lancashire Coastal LMC
North Lancashire PCT